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Building 308/2E
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Dow AgroSciences™

Biopesticides and Pollution Prevention Division
Document Processing Desk (7504C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, Virginia 22202

Attention: Michael Mendelsohn

B.t. CRY34/35Ab1 CONSTRUCT PHP17662 INSECTICIDAL CRYSTAL PROTEIN AS EXPRESSED IN MAIZE
CONFIDIENTIALITY CLASSIFICATIONS FOR NEW EXPERIMENTAL USE PERMIT (68467-EUP-T)

On October 17, 2002, Mycogen Seeds c/o Dow AgroSciences LLC submitted a new application for an Experimental Use Permit to field test the plant-incorporated-pesticide *B.t.* Cry34/35Ab1 Construct PHP17662.

At this time we are identifying the confidentiality classification for all of the Basic Confidential Statement of Formula, Data Matrices, Proposed Labeling, Proposed Experimental Program document, Notice of Filing, Petition for a Temporary Exemption from the Requirement of a Tolerance, and studies we have sent to date.

Hard Copy Correspondence:

Date	Content	Confidentiality Classification
10/17/2002	Basic Confidential Statement of Formula	**C**
	Data Matrix (Agency Internal Use Copy)	**C**
	Data Matrix (Public File Copy)	**A**
	Proposed Labeling	**C**
	Proposed Experimental Program document (excluding Confidential Appendix)	**A**
	Confidential Appendix portion of the Proposed Experimental Program document	**C**
10/22/2002	Data Matrix (Agency Internal Use Copy)	**C**
	Data Matrix (Public File Copy)	**A**
10/22/2002	Notice of Filing	**A**
	Petition for a Temporary Exemption from the Requirement of a Tolerance	**A**
	Data Matrix (Agency Internal Use Copy)	**C**
	Data Matrix (Public File Copy)	**A**
	Proposed Labeling	**C**

Date	Content	Confidentiality Classification
1/15/2003	Proposed Labeling	**C**
	Proposed Experimental Program document (excluding Confidential Appendix)	**A**
	Confidential Appendix portion of the Proposed Experimental Program document	**C**
01/21/2003	Proposed Experimental Program document (excluding Confidential Appendix)	**A**
	Confidential Appendix portion of the Proposed Experimental Program document	**C**

The following information was sent in electronic format. The electronic PDF files that have been sent are classified as "A" and can be posted to the website and viewed by anyone.

Electronic Correspondence:

Date	Content	Confidentiality Classification
1/17/2003	1/15/03 Letter – Request to Amend EUP	**A**
	1/15/03 - Proposed Experimental Program document (excluding Confidential Appendix)	**A**
	12/10/2002 Letter – Amendment to Petition for Temporary Exemption	**A**
	11/25/2002 Letter – Explanation for Heat Lability	**A**
	1/17/2003 Letter – Electronic Copies of Documents for Electronic Dockets	**A**
	1/17/2003 Letter – Electronic Copies of Temporary Tolerance Documents for Electronic Dockets	**A**
	1/17/2002 Letter – Confidential Classification for Study	**A**
	10/17/2002 Letter – Application for New EUP	**A**
	10/17/2002 Data Matrix (Public File Copy)	**A**
	10/17/2002 Proposed Experimental Program document (excluding Confidential Appendix)	**A**
	10/22/2002 Letter – Revised Data Matrix	**A**

Date	Content	Confidentiality Classification
	10/22/2002 Petition for a Temporary Exemption	**A**
	10/22/2002 Notice of Filing Document	**A**
	10/22/2002 Data Matrix (Public File Copy)	**A**
2/5/2003	01/21/2003 Proposed Experimental Program document (excluding Confidential Appendix)	**A**

The following studies are classified as confidentiality classification 'B'.

MRID No.	Study Title
45790401	Characterization of Cry34Ab1 and Cry35Ab1 from Recombinant *Pseudomonas flourescens* and Transgenic Maize
45790601	Product Characterization Data for *Bacillus thuringiensis* Cry34Ab1 and Cry35Ab1 Proteins Expressed in Transgenic Maize Plants (PHP17662)
45808601	Summary of Heat Lability Studies with Cry34Ab1/Cry35Ab1

Below is a list of studies, which are being cited for this submission. Some of these studies were submitted with the request for a new experimental use permit for Cry34/35Ab1 Construct PHP17658 insecticidal crystal protein as expressed in maize (68467-EUP-T) and are classified as confidentiality classification 'B'.

MRID No.	Study Title
45790402	Characterization of DNA Inserted into Transgenic Corn Events E4497.42.1.34, E4497.45.2.16, E4497.59.1.10, E4497.66.1.27, E4497.71.1.29 and E4497.71.1.33
45790403	PS149B1 Binary Insecticidal Crystal Protein: An 8-Day Dietary Study with the Rainbow Trout, *Oncorhynchus mykiss,* Walbaum
45790404	PS149B1 Binary Insecticidal Crystal Protein: An Acute Toxicity Study with the Daphnid, *Daphnia magna* Straus
45790405	PS149B1 Binary Insecticidal Crystal Protein: Dietary Toxicity to Parasitic Hymenoptera (*Nasonia vitripennis*)
45790406	Assessment of Chronic Toxicity of Diet Containing *Bacillus thuringiensis* PS149B1 Insecticidal Crystal Protein to Collembola (*Folsomia candida*)

MRID No.	Study Title
45790407	PS149B1 Insecticidal Crystal Protein: Dietary Toxicity to Green Lacewing Larvae (*Chrysoperla carnea*)
45790408	SDS-PAGE Sensitivity Analysis for Cry35Ab1 in Support of the Simulated Gastric Fluid Digestion Study MRID#45242212
45833201	Quantitative ELISA Analysis of Cry34Ab1 and Cry35Ab1 Proteins Expressed in Maize Plants Transformed with the Vector PHP17662
45790409	Trait Durability and Experimental Use of Transgenic Maize Expressing the Insecticidal Crystalline Proteins Cry34Ab1 and Cry35Ab1
45790410	Field Efficacy of Cry34Ab1/Cry35Ab1 Maize Events Against Corn Rootworms
45242207	PS149B1 14 KDA Protein: Acute Oral Toxicity Study in CD-1 Mice
45242204	Microbial PS149B1 Binary Delta-Endotoxin: Maize-Insect-Pest Susceptibility Study
45242208	PS149B1 44 KDA Protein: Acute Oral Toxicity Study in CD-1 Mice
45242209	PS149B1 14 KDA and 44 KDA Proteins: Acute Oral Toxicity Study in CD-1 Mice
45242212	*In Vitro* Digestibility of PS149B1 Proteins
45584502	*In Vitro* Simulated Gastric Fluid Digestibility Study of Microbially Derived Cry34Ab1 Protein
45242205	Comparison of the Amino Acid Sequence of the Bacillus thuringiensis Strain PS149B1 13.6 kDa and 43.8 kDa Insecticidal Crystal Proteins to Known Protein Allergens
45358401	Thermolability of PS149B1 Binary Delta-Endotoxin
45584501	Heat Lability of Individual Proteins of the PS149B1 Binary ICP
45340701	Microbial PS149B1 Binary Insecticidal Crystal Protein, Pollen Expressing PS149B1 Binary Insecticidal Crystal Protein, and Individual PS149B1 14kDa and 44kDa Insecticidal Crystal Proteins: Evaluation of Dietary Exposure on Honeybee Development

MRID No.	Study Title
45242210	PS149B1 Binary Insecticidal Crystal Protein: A Dietary Toxicity Study with the Ladybird Beetle
45242211	The Tri-Trophic Interaction Between PS149B1 Transformed Maize, Corn Leaf Aphid and Ladybird Beetle
45360201	PS149B1 Binary Insecticidal Crystal Protein: Acute Toxicity to the Earthworm in an Artificial Substrate
45242214	Degradation of Microbial Binary PS149B1 Delta-Endotoxin in a Representative Soil from the Mid-Western USA Maize-Growing Region

If you require further information, please contact me at 317-337-3977 or Jill Achor, Registration Assistant, at 317-337-4660.

Regards,

Penny L. Hunst

Penny L. Hunst, Ph.D.
Regulatory Manager
Regulatory Success-Americas

PLH/jea